

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Dale E. Yelton, et al. Examiner: Not Assigned  
Serial No.: 08/905,293 Group Art Unit: 1815  
Filed: August 1, 1997 Docket: 30436.43USU1  
Title: METHOD FOR INHIBITING IMMUNOGLOBULIN-INDUCED TOXICITY RESULTING  
FROM THE USE OF IMMUNOGLOBULINS IN THERAPY AND IN VIVO DIAGNOSIS

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this Transmittal Letter and the paper, as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on January 29, 1998.

By: 

Sherlin Vaghoubzadeh

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- ☒ Transmittal Sheet in duplicate containing Certificate of Mailing
- ☒ Other: Information Disclosure Statement, Form PTO-1449 and copies of 12 references
- ☒ Return postcard

RECEIVED  
FEB 5 1998  
GROUP 1800

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 13-2724. A duplicate of this sheet is enclosed.

MERCHANT, GOULD, SMITH, EDELL,  
WELTER & SCHMIDT  
Westwood Gateway II, Suite 400  
11150 Santa Monica Blvd.  
Los Angeles, CA 90025  
(310) 445-1140

By: 

Name: Karen S. Canady  
Reg. No.: 39,927  
KSC/WJW/sy



Dkt. 30436.43USU1/KSC/WJW

**UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants : Dale E. Yelton and Mae Joanne Rosok  
Serial No. : 08/905,293 Examiner : Not Assigned  
Filed : August 1, 1997 Group Art Unit: 1815  
For : METHOD FOR INHIBITING IMMUNOGLOBULIN-INDUCED  
TOXICITY RESULTING FROM THE USE OF IMMUNOGLOBULINS  
IN THERAPY AND IN VIVO DIAGNOSIS

11150 Santa Monica Boulevard  
Los Angeles, California 90025  
January 29, 1998

Assistant Commissioner for Patents  
Washington, D.C. 20231

SIR:

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 C.F.R. §1.97(a)**

RECEIVED  
FEB 5 1998  
GROUP 1800

With regard to the above-identified application, applicants are aware of the art listed in the enclosed PTO Form 1449. Applicants call these references to the attention of the Examiner to satisfy disclosure requirements. The enclosed references are indicated as Exhibits 1-12 in the PTO Form 1449.

**FOREIGN PATENT DOCUMENTS**

European Patent Application, EP 0 699 756 A1, published March 3, 1996 (Exhibit 1)

PCT Application No. WO 94/29351, published December 22, 1994 (Exhibit 2)

**OTHER DOCUMENTS**

D. Yelton, et al., "Mutant Monoclonal Antibodies With Alterations in Biological Functions," J. Exp. Medicine, Vol. 56, pp. 1131-1148, October 1982 (Exhibit 3)

Mueller, et al., "Serum Half-Life and Tumor Localization of a Chimeric Antibody Deleted of the C<sub>H</sub>2 Domain and Directed Against the Disialoganglioside GD2," P.N.A.S., Vol. 87, pp. 5702-5705, August 1990 (Exhibit 4)

H. Garrigues, et al., "Detection of a Human Melanoma-Associated Antigen, p97, in Histological Sections of Primary Human Melanomas, Int. J. Cancer, Vol. 29, pp. 511-515, 1982 (Exhibit 5)

Alexander R. Duncan, et al., "The Binding Site for Clq on IgG" Nature, Vol. 332, pp. 738-740, April 1988 (Exhibit 6)

Mi-Hua Tao, et al., "Structural Features of Human Immunoglobulin G That Determine Isotype-Specific Differences in Complement Activation" J. Exp. Med., Vol. 178, No. 2, pp. 661-667, August 1993 (Exhibit 7)

Yuanyuan. Xu, et al., "Residue at Position 331 in the IgG1 and IgG4 Domains Contributes to Their Differential Ability to Bind and Activate Complement" J. Biol. Chem., Vol. 269, No. 5, pp. 3469-3474, February 1994 (Exhibit 8)

A. Morgan, et al., "The N-Terminal End of the C<sub>H</sub>2 Domain of Chimeric Human IgG1 Anti-HLA-DR is Necessary for Clq, FcγRI and FcγRIII Binding" Immunology, Vol. 86, pp. 319-324, 1995 (Exhibit 9)

Mae Joanne Rosok, et al. "A Combinatorial Library Strategy for the Rapid Humanization of Anticarcinoma BR96 Fab," J. Biol. Chem., Vol. 271, No. 37, pp. 22611-22618, September 1996 (Exhibit 10)

Mi-Hua Tao, et al., "The Differential Ability of Human IgG1 and IgG4 to Activate Complement is Determined by the COOH-Terminal Sequence of the C<sub>H</sub>2 Domain," J. Exp. Med., Vol. 173, pp. 1025-1028, April 1991 (Exhibit 11)

I. Hellström, et al., "Strong Antitumor Activities of IgG3 Antibodies to a Human Melanoma-Associated Ganglioside," P.N.A.S., Vol. 82, pp. 1499-1502, March 1985 (Exhibit 12)

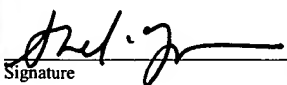
Dale E. Yelton and Mae Joanne Rosok  
U.S. Serial No. 08/905,293  
Filed: August 1, 1997  
Page 3

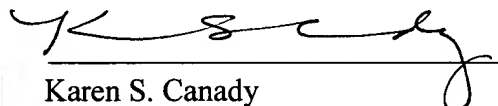
This statement should be considered because it is submitted before the mailing date of a first Office Action on-the-merits. Accordingly, no fee is due for consideration of the items listed on the enclosed PTO Form 1449 (modified).

Applicants hereby fulfill their duty of disclosure. It is believed that the instant application includes claims patentably distinct from the disclosures in the cited prior art, and consideration and allowance of the claims is requested.

Should any fee be deemed due in connection with this filing, applicants authorize the Patent Office to charge Deposit Account No. 13-2724.

Respectfully submitted,

I hereby certify that this paper is being deposited this date with the U.S. Postal Service by first class mail addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.	
 Signature	<u>1/29/98</u> Date

  
Karen S. Canady  
Registration No. 39,927  
Attorney for Applicants  
Merchant & Gould  
Suite 400  
11150 Santa Monica Blvd.  
Los Angeles, CA 90025  
(310) 445-1140